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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/166,298	10/05/98	KIM K	P1092R1

HM12/0214
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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	16

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/166,298	Kim et al.
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Nov 28, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-12* is/are pending in the applicat

Of the above, claim(s) *7, 8, 11, and 12* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6, 9, and 10* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). ~~12~~ filed 6/22/00 & 8/11/00

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed 11/28/00 (Paper No. 15) is acknowledged and has been entered in part. The proposed amendments to the specification detailed on page 2 of the said amendment were not entered because the locations indicated for insertions did not match the directions to make the insertions.

Applicant's ATCC deposit receipt (Exhibit 1) and Declaration (Exhibit 2) filed with the amendment of 11/28/01 are acknowledged.

Claims 1-6 and 9-10 are being examined presently.

The invention being examined is an anti-IFNAR2 mAb, 1D3, which blocks the binding of IFN-αD and which binds to one or more amino acid positions 133, 134, 135 and 139 in situ in the extracellular domain of IFNAR2.

In view of the amendment filed 11/28/00 only the following rejections remain.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite in the recitation of "1D3" because its characteristics are not known. The use of "1D3" monoclonal antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "1D3" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct monoclonal antibodies, cell lines or hybridomas. It is suggested that Applicant amend the instant claim to recite the hybridoma that secretes the claimed antibody.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6 and 9-10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Chuntharapai et al (FASEB J, 4/30/1996, Vol. 10(6), PPA1325, Abstract 1877) as evidenced by Chuntharapai et al (J. Immunol. Vol. 163, pages 766-773, 1999).

Chuntharapai et al (FASEB J) teach the anti-IFNAR monoclonal antibody 1D3. It is an inherent property of 1D3 that it meets all the limitations of the instant claims as evidenced by Chuntharapai et al (J. Immunology). ID3 is an IgG2a isotype monoclonal antibody (especially Table 1, line 1) that blocks the binding of IFN-α1(IFN-αD), IFN-α2, IFN-α5 and IFN-α8, but not IFN-β (especially page 768, column 2, lines 34-41). ID3 recognizes an epitope (especially page 768, column 2, lines 6-10) spanning amino acid residues 133-139 and 153-157 (especially Table IV, page 769 column 2, lines 1-2).

With regard to the instant claims, the property of blocking the binding of a first type I IFN to IFNAR2 but not the binding to a second type I IFN is considered an inherent property of the reference compound, as is the property of binding to specific residues. The claimed molecule appears to be the same as the art absent a showing of any differences. Since the Patent Office does not have the facilities for examining and comparing the molecule of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The reference teachings anticipate the claimed invention.

Applicant's arguments filed 11/28/00 have been fully considered but they are not persuasive.

It is Applicant's position that the disclosure of Chuntharapai et al is not enabling in : (1) that methods or conditions for detecting or selecting for antibodies that display the properties of both blocking the binding of IFNAR2 to a first type I interferon but not to a second type I interferon, (2) that Chuntharapai et al fails to enable production of the immunogen used to generate the antibodies, (3) that the Chuntharapai et al abstract did not place the 1D3 antibody at the disposal of the practitioner and (4) that with respect to claim 6, that the said abstract fails to teach an anti-IFNAR2 monoclonal antibody that binds to the residues recited in the said claim because it does not recite the said residues and does not provide a teaching to mutate those specific residues for mapping studies.

It is the Examiner's position that the disclosure of Chuntherapai is enabling in: (1) that Chuntherapai does teach an assay to determine the ability of the antibodies to block binding of biotinylated IFN-aA/D to IFNAR2 and by their ability to inhibit the anti-viral cytopathic effect of various IFNs and that several of the monoclonal antibodies showed "partially blocking activity", (2) that Chuntherapai et al teach IFNAR2 on human myeloma U266 cells, identifies IFNAR2 as the human interferon-α-receptor, an essential component of the multi-chain

interferon receptor complex and teaches a molecular weight of 115 Kd and furthermore, that the said receptor is admitted prior art (specification at page 1 at lines 25-27), (3) that Applicant is reminded that the instant claims are not drawn to a monoclonal antibody produced by a specifically deposited hybridoma, (4) that the abstract teaches alanine scanning as a method to identify which residues are being bound by the antibodies.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the aplicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 1-6 and 9-10 stand provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 9-10 of copending Application No. 08/943,771. This is a provisional double patenting rejection since the conflicting claims have ct patented.

It is noted by the Examiner that the Applicant has requested that this rejection be held in abeyance until there is an indication of allowable subject matter, however, the Examiner is obligated to maintain the rejection.

8. The reference "6" crossed out in Applicant's IDS filed 6/22/00 has already been considered and was provided in the previous Office Action mailed 5/22/00.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Group 1640
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February 8, 2000

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